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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,254	07/18/2003	Nobuaki Honda	03419/LH/DH	2857

1933 7590 10/17/2005

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EXAMINER	
ROGERS, KRISTIN D	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/623,254	HONDA ET AL.	
	Examiner	Art Unit	
	Kristin D. Rogers	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

KDR

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-5 are drawn to a subcombination of the sampling syringe unit, classified in class 600, subclass 576

   II. Claims 6-11 is drawn to a combination of a sampling device, classified in class 600, subclass 576.

2. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the protective member set forth in claim 1. The subcombination has separate utility such as the ability to function in related hand-held applications.

3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Leonard Holtz on September 20, 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

DETAILED ACTION

Information Disclosure Statement

6. The information disclosure statement filed 07/18/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. An English translation of Japanese Patent No. 3155523 and Japanese Patent Publication No. 2000-185034 were not filed with the IDS, and therefore were not considered.

Specification

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1 through 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Vaughn (5662127) in view of Frazier et al. (WO 01/93930 A1) and Erez et al. (6290683).

In regards to claims 1 and 2, De Vaughn shows a disposable blood withdrawal syringe **20**, syringe base **21**, a diaphragm attached to syringe base defining a chamber in cooperation with syringe base **32**, and a skin piercing needle or lancet **40**. Devaughn lacks the hollow tubular needle and a protective member having an aperture for passing needle therethrough. Frazier et al. teaches an active needle device that it is known to use a needle **10** with a hollow elongated shaft **11** as set forth in the abstract to provide a means for fiuid injection or extraction. Erez et al. teaches a skin piercing needle assembly that it is known to use a needle assembly **11** for passing a needle **12** through

an aperture **19** formed in a plate placed between the needle assembly and a body to be pierced by the needle **12**, the needle assembly **11** including a needle **12** having a needle point **13**, a needle protector **18** including a sleeve **17** associated with the needle **12**, wherein at least a portion of the sleeve has elastic properties in a generally longitudinal direction and is adapted to take up a generally extended state when the assembly is in a non-operative orientation so as to surround a portion of the needle including the needle point **Figure 4A**, and is further adapted to take up a compressed state when the assembly is in an operative orientation so as to expose a portion of the needle including the needle point, the needle point passing through the aperture in the operative orientation **Figure 4B** as set forth in column 1, lines 65-67 and column 2, lines 1-12 for reduced risks of accidental puncture by needle or exposure to contamination. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by De Vaughn with a hollow needle and a protective member as taught by Frazier et al. and Erez et al., since such modifications would provide the device with a hollow needle and a protective member for providing a means to extract blood or body fluid and further protection from accidental needle puncture and contamination.

In regards to claim 3 De Vaughn shows a blood withdrawal syringe with a needle **40** that protrudes from the central portion **24** of the syringe base **21** but does not disclose expressly the outer diameter of the hollow needle device. Frazier et al. teaches an active needle device comprising a hollow microneedle having a width that can range from 0.05μm to 1mm, page 9, lines 30-31. It would have been obvious to a

person of ordinary skill in the art to modify the device as taught by De Vaughn with the hollow microneedle taught by Frazier et al., because the Applicant has not disclosed that having a needle with an "outer diameter of 0.1mm or less" provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a hollow microneedle as taught by Frazier et al., because it provides extraction of small amounts of fluid and minimal tissue damage, and since it appears to be an arbitrary consideration which fails to patentably distinguish over Frazier et al.

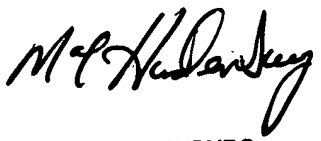
In regards to claims 4 and 5, De Vaughn shows a communication passage **25** connecting the chamber **29** and needle **40** arranged parallel with the diaphragm **32**, but does not teach integrating electrodes into the communication passage **25**. Frazier et al. teaches that it is known to use active components such as actuators and sensors **17** placed or integrated into the hollow elongated shaft **11** of a microneedle **21**, the hollow elongated shaft defines one channel **12** therethrough providing communication between at least one input port **15** and at least one output port **16** of the needle device **10** as set forth on page 3, lines 5-9, to provide facilitation for analyzing a substance sampled through the needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of De Vaughn to have sensors or actuators (i.e., electrodes) in the communication passage **25** as taught by Frazier et al., since such a modification would provide the device with integrated sensing capabilities for providing analyses of blood or body fluid sampled through the needle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDR



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